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EXAMINER

BADIO, BARBARA P

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/922,532
Filing Date: August 03, 2001
Appellant(s): SCHERSL ET AL.

Valerie Friedrich
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 1, 2008 appealing from the Office action mailed October 25, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,495,094	CLEARY	1-1985
5,952,393	SORKIN, JR.	9-1999

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6,394,230	MILSTEIN et al.	5-2002
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0,952,208	FUENZALIDA et al.	10-1999
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JONES et al., "Short-Term Administration of Tall Oil Phytosterols Improves Plasma Lipid Profiles in Subjects With Different Cholesterol Levels.". *Metabolism*, Vol. 47(6), (June 1998), pages 751-756.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 57 and 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuenzalida et al. (EP 952,208), Sorkin, Jr. (US 5,952,393), Gamble et al. (US 6,596,776), Cleary (US 4,495,094); Milstein et al. (US 6,394,230) and Jones et al. (*Metabolism*, 1998) in combination.

Each of Fuenzalida, Sorkin and Gamble teaches policosanols, i.e., long chained aliphatic alcohols, are useful in lowering plasma cholesterol levels (see each reference in its entirety, especially Fuenzalida et al., sections 0003-0007, 0050, 0057, 0068, 0071 and 0076; Sorkin, Jr., col. 1, lines 5-8; col. 3, lines 11-26; examples 1 and 2; Gamble et al., col. 2, lines 4-21 ; col. 3, line 52 - col. 4, line 39; col. 9, lines 44-63).

Fuenzalida teaches the presence of fatty alcohols such as eicosanol, docosanol, tetracosanol and hexacosanol in tall oil (see especially Example 9, Table 4) and Cleary teaches the presence of octadecanol in tall oil (see the reference in its entirety, especially Example II).

Each of Gamble, Milstein and Jones teaches the incorporation of the cholesterol-lowering agents, such as mixtures of aliphatic alcohols, into food substances such as

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margarine is known in the art (see each reference in its entirety, especially **Gamble et al.**, col. 9, lines 52-63; **Milstein et al.**, col. 1, lines 18-35; **Jones et al.**, page 751, 1st paragraph).

Based on the prior art as discussed above, the utilization of a composition comprising long chained aliphatic alcohols in lowering plasma cholesterol levels would have been obvious to the skilled artisan in the art at the time of the present invention.

The instant claims differ from the cited prior art by reciting specific ranges of eicosanol, docosanol, tetracosanol and hexacosanol with or without a specific amount of octadecanol. However, determination of the amounts of each of the alcohols in the composition that would be effective in lowering cholesterol level requires only routine experimentation which was within the level of skill of the ordinary artisan in the art at the time of the present invention. Therefore, the recitation of specific ranges of the active ingredients is not patentable absence a showing of criticality which is not present in the present specification.

(10) Response to Argument

Applicant argues the claimed policosanol composition is strikingly different from that of the cited references and that the references, singularly or in combination, do not teach, suggest or anticipate the present composition. According to applicant, (a) Fuenzalida teaches fatty alcohols but does not teach said compounds are cholesterol lowering agents, (b) the policosanol composition of Sorkin and Gamble, known for cholesterol lowering activity, contain eight or nine different policosanols with carbon numbers ranging from 18 to 36, (c) the skilled artisan in the art would not assume all

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plant alcohols, no matter the carbon number would have cholesterol lowering effect even though, the art shows that alcohols with higher carbon numbers have said effect, (d) there is substantial uncertainty on the effect of even small changes in the constituents of a policosanols mixture on its hypocholesterolemic activity, (e) policosanols from different natural sources exhibit different therapeutic effects and (f) the examiner has not cited a reference which shows a single policosanols, not in a mixture, having cholesterol lowering effect. Applicant's argument was considered but not persuasive for the following reasons.

The examiner agrees that Fuenzalida does not teach policosanols are cholesterol lowering agents. As noted by applicant, said teaching is found in both Sorkin and Gamble. However, applicant argues the compositions of Sorkin and Gamble contain eight or nine different policosanols. The examiner notes the recitation of the transitional term "comprising" in the instant claims which is inclusive or open-ended and, thus, does not exclude additional, unrecited elements or method steps (see MPEP 2111.03). Therefore, the instant claims are not limited to the four recited policosanols but could include the other alcohols taught by the prior art.

In response to applicant's argument that the examiner has not cited a reference showing a single policosanols, not in a mixture, having cholesterol lowering effect. Applicant's attention is directed to applicant's own remarks dated June 17, 2004, wherein applicant admits the art teaches octacosanol and hexacosanol have cholesterol lowering effect. Note the quotations between:

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As far as the effect of individual alcohols concerns, only octacosanol (Kat, S et al., quoted in "other references" in Sorkin) and hexacosanol (JP-A-62099323) have been investigated and shown to have cholesterol lowering effect.

(see page 7 of applicant's remarks dated June 17, 2004). It is noted that Sorkin is one of the references cited in the instant rejection.

(a) The Skilled Person

The pertinent art of the invention is related to human health and nutrition, therefore the skilled person knows about the health adverse effects of high serum cholesterol levels and is also aware of the current dietary or pharmacological approaches to reduce said levels. Dietary measures the person of skill is aware of, include daily intake of certain amounts of phytosterols or certain long chain fatty alcohol or mixtures of long chain fatty alcohols. The person of skill is aware as well of the mechanism of action of the phytosterols in reducing serum cholesterol levels. The biochemical basis for the action of phytosterols have been elucidated, and it is related to their structural similarity to cholesterol. With respect to the effect of long chain aliphatic alcohols on serum cholesterol levels, the current state of empirical knowledge can be summarized as follows:

- Hexacosanol (C26) and octacosanol (C28) each one separately, are effective;

(see page 10 of applicant's remarks dated June 17, 2004).

Additionally, it is applicant's position that pure hexacosanol and pure octacosanol showed no statistically significant cholesterol-lowering effect (US Patent No. 5,663,156). Examination of the cited reference (a) shows the effect was not statistically significant and not that the compounds do not possess said activity, (b) shows the effect of a single dose, i.e., 5mg/kg and, thus, said amount might not be therapeutic and (c) does not show the effect of the combination of the two at the same dose. The skilled artisan evaluating the reference would have the reasonable expectation that increase amounts of the compounds will have greater cholesterol- lowering effect and he would also have

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the reasonable expectation that combination of the two compounds in the amount taught by the reference will have an additive effect and, thus, a greater cholesterol-lowering effect. There is no evidence of record showing that said expectation would be wrong. Again, the examiner notes as stated above, that both hexacosanol and octacosanol are known in the art to have cholesterol-lowering effect.

Applicant also argues (i) the skilled artisan would not assume all plant alcohols, no matter the carbon number would have cholesterol lowering effect, even though, the art shows higher carbon number alcohols are effective, (ii) there is uncertainty of the effect of small changes in the constituents of a policosanols mixture and (iii) policosanols from different natural sources exhibit different therapeutic effects.

First, identical compounds, irrespective of the source, would be expected to have identical properties. Said fact is well known within the chemical, medical and pharmaceutical arts. Therefore, identical mixtures of policosanols, i.e., identical compounds and identical amounts of each compound in said mixtures, would be expected to have identical effects. Applicant refers to US Patent No. 6,465,526 in support of the argument that policosanols from different natural sources exhibit different therapeutic effects. However, as noted in a previous Office Action, the reference does not show the make-up of each mixture and, thus, one cannot assume the difference in activity is due to the source from which it was obtained and not the makeup of the compositions utilized.

Secondly, the issue is one of a mixture of policosanols having cholesterol-lowering effect. Compositions comprising a mixture of policosanols are taught by the art

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(see Fuenzalida, Sorkin and Gamble). The art also teaches the cholesterol-lowering property of policosanol mixture (see Sorkin and Gamble). Even if one agrees that not all plant alcohols would have cholesterol lowering effect, the art teaches a mixture of higher molecular weight aliphatic alcohols have said effect.

Lastly, applicant argues there is uncertainty as to the effect of small changes in the constituents of a mixture of policosanol. However, the skilled artisan in the art would expect that there is an optimum amount of each policosanol in the mixture that would be necessary to obtain the desired effect and deviation would result in variation of the effect produced. Said variation of effect due to any change in the constituents and/or amount of each constituent is expected. Thus, applicant's argument is noted but not persuasive.

In summary, based on the level of skill of the ordinary artisan in the art at the time of the present invention and the teaching of the cholesterol-lowering effect of policosanol mixtures containing eicosanol, docosanol, tetracosanol and hexacosanol, the optimization of said mixture would require only routine experimentation which is within the level of skill of the ordinary artisan in the pharmaceutical art. When the difference between the claimed invention and the prior art is one of concentration/amounts, the burden is on applicant to show that said proportions are critical to the claimed invention. It is the examiner position that applicant has not provided evidence as to the criticality of the recited ranges that would make the claimed composition unobvious and unexpected to one of skilled in the art at the time of the present invention.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Barbara P. Badio, Ph.D./
Primary Examiner, Art Unit 1612

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/Frederick Krass/
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